

Efficacy Evaluation And Technical Management Section
EFFICACY REVIEW - I
ANTIMICROBIAL PROGRAM BRANCH

IN 04-15-95 OUT 05-21-96
Reviewed by Bruce H. Mann Date 05-21-96

LAN Code _____

EPA Reg. No. or File Symbol # 1839-95

EPA Petition or EUP No. None

Date Division Received 02-26-96

Type Product Hospital Disinfectant

MRID No (s) Data submitted under MRID's 4393763-01.

Product Manager PM-31 (Johnson)

Product Name NP 4.5 D & F Detergent/Disinfectant

Company Name Stepan Company

Submission Purpose An amendment to add additional test organism
"methicillin resistant Staphylococcus aureus"
to the product proposed label dated 02-26-96.

Type of Formulation A liquid concentrate to be diluted for use.

<u>Active Ingredient (s):</u>	<u>%</u>
n-Alkyl (C14, 60%; C16, 30%; C12, 5%; C18, 5%)	
dimethyl benzyl ammonium chlorides	2.25
n-Alkyl (C12, 68%; C14, 32%)	
dimethyl ethylbenzyl ammonium chlorides	2.25

200.0 Introduction

200.1 Uses: Refer to the proposed label, dated 08-31-95. Also, refer to the latest accepted label dated 09-19-89.

200.2 Background Information:

The current submission received 04-15-96, is a registered one-step disinfectant cleaner for hospital or general use areas. The current submission is an amendment which includes a proposed disinfectant efficacy claim for the addition of methicillin resistant Staphylococcus aureus

201.0 Data Summary:

201.1 Brief Description:

Efficacy Data report for "NP 4.5 (D & F)" (EPA Reg. No. 1839-95)-Organic Soil Load. The study was submitted by Victor Viasaty, Stepan Company, Northfield, IL 60093

201.2 Test Summaries:

Disinfection-Additional Test Data with Organic Soil.

1. Method: AOAC Use dilution Method, 16th ed., 1995.
Samples tested: Ref no. 1900-48 and no. 1900-49.
2. Modifications: 5% (v/v) horse serum included with the bacterial inoculum.
Bacterial survival on carriers determined after drying onto the surface at 36°C for 40 minutes.
3. Dilution: Tested at 2 ounces/gallon (2:128) by adding 4mls of test substance to 252 mls of sterile deionized water.
4. Exposure: 10 minutes at 20°C.
5. Results: The tested products showed no growth in any of the 10 primary subcultures tubes after a 10 minute exposure time in the presence of a 5% horse serum load.
6. The tested products showed satisfactory performance as a disinfectant against the additional test microorganism under the test conditions when used at a dilution of 2 ounces/gallon.

202.0 Recommendations:

202.0 Claims Related to Human Health:

202.1 Efficacy Supported by the Data:

The submitted efficacy data generated by the AOAC Use Dilution Test Method are acceptable to support effectiveness of the product as a one-step cleaner disinfectant in the presence of light or moderate amount organic soil (5%) horse serum for hospital use (vs. Staphylococcus aureus methicillin resistant) on hard nonporous, surfaces which are thoroughly wetted by the solution and allowed to remain wet for a contact time of 10 minutes before wiping.

203.0 Labeling comments:

The subject product proposed label NP 4.5 (D & F) Detergent Disinfectant dated 02-26-96 should be revised to reflect the following instructions:

1. On the middle panel of the proposed label, there are no adverse comments.
2. On the left panel, and under virucidal activity, revise the phrase "... on environmental, inanimate hard surfaces..." to read "... on environmental, inanimate hard nonporous surfaces...".
3. There are no adverse comments on the right panel.